

JUL 16 2004

Empower Transfer Set 510(k) Summary

Submitter's Information:	E-Z-EM, Inc. 717 Main Street Westbury, NY 11590
Telephone Number:	(516) 333-8230, ext. 2345
Fax Number:	(516) 333-8278
Contact:	Steven Hartman, Senior Project Engineer, CT Injectors
Date Prepared:	June 28, 2004
Trade Name:	Empower™ Transfer Set
Common Name:	Transfer Set
Classification Name:	Tubing, Fluid Delivery [21 CFR 880.5440] Product Code: FPK Regulatory Class: II
Predicate Device:	Venusa Flu Ven Tr-1 (K791131)
Indications for Use:	The Empower Transfer Set is intended to deliver fluid (contrast media or saline) from a container into a CT power Injector syringe.
Device Description:	The Empower Transfer Set is a disposable set used to transfer contrast media or saline from a container that can be spiked to a CT power Injector syringe.

Comparative Summary Tables

A summary of the proposed device as compared to the predicate device is as follows:

Parameter	Proposed E-Z-EM Empower Transfer Set	Predicate Venusa Flu Ven Tr-1 (K791131)
Indication For Use	It is intended to be used in the delivery of fluid (contrast media or saline) into a syringe.	The device has been categorized for use of I.V. fluid transfer.
Female Luer	Polycarbonate, Clear	Same
Clamp	Pinch clamp	Same
Spike	Vented Spike	Same
Tubing	6" Length PVC – Medical Grade	7" Length Same
Connection method	ISO 594 Luer	Same
Sterility	Ethylene Oxide (EtO) sterilized	Same
Biocompatibility	Tested to ISO 10993-1 and 10993-7	Same



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUL 16 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Steven Hartman
Senior Project Engineer
E-Z-EM, Incorporated
717 Main Street
Westbury, New York 11590

Re: K041178
Trade/Device Name: Empower Transfer Set
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPK
Dated: May 4, 2004
Received: May 5, 2004

Dear Mr. Hartman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

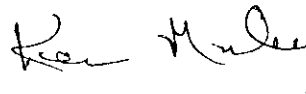
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



for

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041178

Device Name: Empower Transfer Set

Indications For Use:

The Empower Transfer Set is intended to deliver fluid (contrast media or saline) from a container into a CT power Injector syringe.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Shere Naveau for A.D.U.

(Division Sign-Off)

Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K041178